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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,150	07/17/2003	Robert W. Childers	DI-5828	5656
29200 7590 09/04/2007 BAXTER HEALTHCARE CORPORATION 1 BAXTER PARKWAY DF2-2E DEERFIELD, IL 60015			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,150

Applicant(s)

CHILDERS ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 13-18, 20, 22 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Roberts discloses a system for providing peritoneal dialysis to a patient, the system comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 1 on page 377 discloses that a double lumen catheter would be advantageous to use); a fluid circuit in fluid communication with the catheter, the fluid circuit consisting of: a fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient via only a single loop of the fluid loop (col. 1, page 377 discloses in the second paragraph a single loop that is a modification of the single fluid loop disclosed in the paragraph above and in Fig. 12); a supply of dialysate (second paragraph in first column of page 377 discloses a supply of dialysate); a chamber coupled to the fluid loop through which the dialysate can be fed at a feed rate into the fluid loop (Fig. 7 discloses that Kraus uses a chamber (labeled as A; this can be interpreted as a chamber, as the definition of a "chamber" according to the Cambridge dictionary online is: "an enclosed space in a

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machine, plant or animal".

{<http://dictionary.cambridge.org/define.asp?key=12414&dict=CALD>}) that is coupled to the fluid loop and which the dialysate is fed through (see arrows going through A), and since Applicant does not specify anything about the feed rate (i.e. whether it is the same or different than the other rates, or specific velocities, etc.) the rate at which the dialysate flows through the chamber (A), can also be considered the chamber's "feed rate"); a cyclor that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove therapeutic effective amount of solutes and excess water from the patient (since the fluid circuit disclosed in the second paragraph of col. 1 on page 377 is a modification of Fig. 12, see Fig. 12 for the cyclor labeled as "pump"); and a discharge fluid path coupled to the fluid loop through which the dialysate is drained from the fluid circuit (second paragraph of col. 1 on page 377 discloses that there is a discharge fluid path, as "the outflow of the spent peritoneal would be adjusted to the inflow") at a discharge rate that is less than the circulation rate allowing dialysate to be circulated a plurality of times along the fluid loop prior to discharge (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same

researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377).

In reference to claim 14, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 16, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min).

In reference to claim 17, Roberts discloses that the chamber is capable of mixing and heating the dialysate (Fig. 7 and 12, specifically Fig. 12 discloses a heater).

In reference to claim 18, Roberts discloses that the chamber (A) is coupled to the fluid loop via a fluid supply path (fig. 7 discloses that A is coupled to the fluid loop and the fluid supply path is indicated as the arrows around the loop, specifically the arrow leading to I).

In reference to claim 20, Roberts discloses that the chamber is directly coupled to the fluid loop (Fig. 7 discloses that the chamber (A) is directly coupled to the fluid loop).

In reference to claim 22, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claims 23, Roberts discloses a chamber (Fig. 7, labeled as "A") in communication with the fluid loop such that the fluid loop can accommodate a variable increase in the dialysate during treatment and that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

Claims 24-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Roberts discloses a system for providing peritoneal dialysis to a patient, the system comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 1 on page 377 discloses that a double lumen catheter would be advantageous to use); a fluid circuit in fluid communication with the catheter, thereby defining only a single fluid loop capable of circulating dialysate into, through and out of a peritoneal cavity (col. 1, page 377 discloses in the second paragraph a single loop that is a modification of the single fluid loop disclosed in the paragraph above and in Fig. 12), the fluid circuit includes: a supply of dialysate coupled to the fluid loop (second paragraph in first column of page 377 discloses a supply of dialysate); a cyclor that pumps the dialysate into the fluid loop at a feed rate and circulates the dialysate along the fluid loop at a circulation rate to remove therapeutic effective amount of solutes and excess water from the patient (since the fluid circuit disclosed in the second paragraph of col. 1 on page 377 is a modification of Fig. 12, see Fig. 12 for the cyclor labeled as "pump"); a cleaning device coupled to the fluid loop via a cleaning fluid path wherein the dialysate can be fed into the cleaning fluid path and

cleaned at a cleaning rate prior to reintroduction into the fluid loop (Roberts discloses in Fig. 7 that a cleaning device (A) is used. As applicant does claim any specifics as to what the cleaning device must have, contain, etc. the hemofilter therefore is being interpreted as a cleaning device, as the hemofilter (A) is coupled to the fluid loop (Fig. 7), and the cleaning fluid path is the path through which the dialysate flows through A, and since it is a filter, it inherently removes unwanted particles from the dialysate, therefore acting as a cleaning device. Also, as Applicant does not claim any specifics as to whether the cleaning rate is the same as, less than, a specific rate, etc. the rate that the dialysate flows through the cleaning device (A) is being interpreted as the cleaning rate); and a discharge fluid path coupled to the fluid loop through which the dialysate is drained (second paragraph of col. 1 on page 377 discloses that there is a discharge fluid path, as "the outflow of the spent peritoneal would be adjusted to the inflow") at a discharge rate effective to circulate the dialysate a plurality of times along the fluid loop prior to discharge (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377).

In reference to claim 25, Roberts discloses that the fluid loop is coupled to the supply of dialysate, the cleaning fluid path and the discharge fluid path via a cyclor (Figs. 7 and 12; see Fig. 12 for the cyclor labeled as "pump").

In reference to claim 26, Roberts discloses that the cyclor includes a fluid circuit coupled to a pumping mechanism and a plurality of valves such that the cyclor is capable of automatically controlling the flow of dialysate into and out of the fluid loop during treatment (Figs. 7 and 12, specifically fig. 12 discloses valves).

In reference to claims, 27 and 28, Roberts discloses that the cleaning device contains a sorbent material (Fig. 6 discloses using a sorbent cartridge) capable of non-selective removal of solutes from the dialysate prior to reuse and that the sorbent material is carbon (col. 1, paragraph 3, line 1).

In reference to claim 29, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 30, Roberts discloses a chamber (Fig. 7, labeled as "A") in communication with the fluid loop such that the fluid loop can accommodate a variable increase in the dialysate during treatment and that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2 and 5-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Roberts discloses the device substantially as claimed, including: a system for providing peritoneal dialysis to a patient, the system comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 1 on page 377 discloses that a double lumen catheter would be advantageous to use); a fluid circuit in fluid communication with the catheter, the fluid circuit consisting of: a single fluid loop only, the fluid loop configured to circulate dialysate into, through and out of a peritoneal cavity of the patient (col. 1, page 377 discloses in the second paragraph a single loop that is a modification of the single fluid loop disclosed in the paragraph above and in Fig. 12); a supply of dialysate coupled to the fluid circuit (second paragraph in first column of page 377 discloses a supply of dialysate); at least one of a cleaning device coupled to the fluid loop via a cleaning fluid path wherein the dialysate can be fed into the cleaning fluid path and cleaned at a

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cleaning rate prior to reintroduction into the fluid loop (Roberts discloses in Fig. 7 that a cleaning device (A) is used. As applicant does claim any specifics as to what the cleaning device must have, contain, etc. the hemofilter therefore is being interpreted as a cleaning device, as the hemofilter (A) is coupled to the fluid loop (Fig. 7), and the cleaning fluid path is the path through which the dialysate flows through A, and since it is a filter, it inherently removes unwanted particles from the dialysate, therefore acting as a cleaning device. Also, as Applicant does not claim any specifics as to whether the cleaning rate is the same as, less than, a specific rate, etc. the rate that the dialysate flows through the cleaning device (A) is being interpreted as the cleaning rate); a cyclor that pumps the dialysate into the fluid circuit at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove therapeutic effective amount of solutes and excess water from the patient (since the fluid circuit disclosed in the second paragraph of col. 1 on page 377 is a modification of Fig. 12, see Fig. 12 for the cyclor labeled as "pump"); and a discharge fluid path coupled to the fluid loop through which the dialysate is drained from the fluid circuit (second paragraph of col. 1 on page 377 discloses that there is a discharge fluid path, as "the outflow of the spent peritoneal would be adjusted to the inflow") at a discharge rate that is less than the circulation rate allowing dialysate to be circulated a plurality of times along the fluid loop prior to discharge (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow

and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377).

Roberts, however, does not disclose a chamber coupled to the fluid loop (the setup described above and disclosed in Roberts does not disclose an additional chamber). Roberts does, however, disclose a similar peritoneal dialysis system (Fig. 6) that also includes a chamber (the bubble trap disclosed in Fig. 6 is being interpreted as a chamber, as the definition of a "chamber" according to the Cambridge dictionary online is: "an enclosed space in a machine, plant or animal".

{<http://dictionary.cambridge.org/define.asp?key=12414&dict=CALD>}) Furthermore, since Applicant does not specify anything about the feed rate (i.e. whether it is the same or different than the other rates, or specific velocities, etc.) the rate at which the dialysate flows through the chamber (bubble trap), can also be considered the chamber's "feed rate"). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the system described by Roberts in the preceding paragraph with the chamber (bubble trap) as taught by a similar system disclosed by Roberts (Fig. 6) in order to provide another means for controlling flow, and additionally the chamber/bubble trap is a well known addition to existing dialysis systems, as the system in Fig. 5 disclosed by Roberts also includes a chamber/bubble trap.

In reference to claim 2, Roberts discloses that the feed rate and the discharge rate are less than the circulation rate (paragraph 2, col. 1, page 377 discloses using inflow and outflow rates of 30 ml/min while using a higher circulation rate. Also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged).

In reference to claim 5, Roberts discloses that the circulation rate is about 300 ml/min or less (Roberts discloses in paragraph 1, col. 1 on page 377, the unmodified circuit in Fig. 12 uses a rate of 200 ml/min which is less than 300. Also, paragraph 2, col. 1, page 377 discloses using a rate of 200 ml/min).

In reference to claim 6, Roberts discloses that the supply of dialysate contains about 25 liters or less of dialysate (Fig. 12, which is circuit that modified circuit of paragraph 2 is based on, uses 20 L of dialysate, which is less than 25 L).

In reference to claim 7, Roberts discloses that the dialysate is continuously fled, circulated and drained over a treatment period of about 8 hours or less (paragraph 2, col. 1, page 377 discloses the fluid circuit referenced in claim 1, which is based off of the circuit in the paragraph above, which teaches an 8 hour treatment).

In reference to claim 8, Roberts discloses that the dialysate is infused into the peritoneal cavity of the patient and an additional volume of the dialysate is subsequently and continuously fed into the fluid circuit during treatment (paragraph 2, col. 1, page 377).

In reference to claim 9, Roberts discloses that the initial volume of the dialysate is circulated along the fluid loop during an initial treatment period without the continuous feed of the additional volume of the dialysate into the fluid loop and the continuous discharge of dialysate from the fluid loop (paragraph 2, col. 1, page 377).

In reference to claims 10 and 11, Roberts discloses a chamber (Fig. 7, labeled as "A") in communication with the fluid loop such that the fluid loop can accommodate a variable increase in the dialysate during treatment and that the increase is due to an addition of ultrafiltrate to the fluid loop (paragraph 2, col. 2 of page 374).

In reference to claim 12, Roberts discloses that the feed rate and the discharge rate are alternatively varied to create tidal CFPD (paragraph 2, col. 1, page 377).

Claim 3, 4, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration"). Roberts discloses the device substantially as claimed including the feed rate and the discharge rates being lower than the circulation rate (col. 1, second paragraph on page 377 discloses that the inflow and outflow of dialysate are set to equal each other, at a rate of 30 ml/min and that the fluid in the peritoneum is at a higher circulation rate; also see paragraph 2, col. 2 of page 374 which discloses the same author cited as using circulation rate of 200 ml/min and inflow and outflow rates of 36 ml/min thus allowing the fluid in the peritoneum to circulate several times before being discharged. These rates of 200 and 36 are from the same researcher (Kraus et al.) that is being quoted in the second paragraph of col. 1, page 377). Roberts,

however, does not disclose that the feed and discharge rates are maintained equally at a rate that is either one-half or one-third of the circulation rate, such that the dialysate circulates either two or three times along the fluid loop. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Roberts such that the feed and discharge rates are either one-half or one-third the circulation rate, because it is a mere manipulation or arithmetic in order to derive a circulation of two or three times around the loop, and because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. ("Innovative Peritoneal Dialysis: Flow-Thru and Dialysate Regeneration") in view of Dadson (WO 99/06082). Roberts discloses the device substantially as claimed except for the dialysate being contained in four separate containers. Dadson, however, discloses a peritoneal dialysis system which uses four separate containers of dialysate (Figs. 6, 7 and 9). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have used multiple containers, such as the four separate dialysate containers as taught by Dadson (Figs. 6, 7 and 9), in order to provide back up reservoirs in case one malfunctions, as well as to provide an adequate supply of dialysate depending on the treatment plan.

Response to Arguments

Applicant's arguments with respect to claims 1-30 have been considered but are moot in view of the new ground(s) of rejection.

Upon further review of the Roberts reference and further review of Applicant's claim language, it is the examiner's position that Roberts still applies as a reference against Applicant's pending claims, as it is now the examiner's position that the claim terminology "a chamber" and "a cleaning device" are relatively broad terms. As argued above, it is the examiner's position that Roberts still anticipates and is obvious over Applicant's claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS.
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons